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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/516,419

08/29/2005

Claude R Mallet

60008US(49991)

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06/02/2008

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EXAMINER

GITOMER, RALPH J

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

06/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/516,419 | Applicant(s) MALLET ET AL. | |
| | Examiner Ralph Gitomer | Art Unit 1657 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/20/08, 4/4/08</u> | 6) <input type="checkbox"/> Other: _____ |

The RCE received 5/12/08 has been entered and claims 1-16 are currently pending in this application. A single species of surfactant has been elected as applied to method claims 1-16 as seen on page 14 of the specification, no claim is limited to the elected specie. Please provide a publication date for reference CA, Exhibit A.

The invention as described in the specification is directed to analysis of a small molecule obtained by lysis of cells with a surfactant where the surfactant is removed prior to mass spec analysis. The improvement is using a specific surfactant with similar properties to SDS but degrades in acid and thereby can be readily removed. The specification defines small molecule on page 6 first paragraph as all molecules with an atomic mass of less than about 1000.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Lee in view of Schneider.

Lee (WO 00/70334 A1) entitled "Destructible Surfactants and Uses Thereof" teaches on page 1 methods for analysis of large molecules such as proteins and peptides with surfactants that can be destroyed at low pH levels. On page 5 lines 15-18 the surfactants may be used in applications which benefit from the initial presence and ultimate removal of a surfactant such as solubilization, analysis, separation, purification and/or characterization of large molecules. On page 12 the same compound as presently elected is disclosed. See the claims which simple refer to a sample and do not refer to its molecular weight.

The claims differ from Lee in that they specify the method is for analysis of a small molecule where the references refer to large molecules.

Schneider (US 2005/0153346) entitled "Methods for Conducting Metabolic Analyses" teaches in paragraph 125, mass spectrometry can be used according to known methods to determine the masses of relatively small molecules as well as relatively large molecules. MALDI is among the most commonly used mass spectrometric techniques.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the surfactant taught by Lee who analyzes large molecules to also analyze small molecules because the surfactant of Lee would have the same function irrespective of the type of analyte. Lee shows that it is desirable to use the presently elected surfactant to improve the analysis of the digests. So to begin with small molecules and analyze them would be a subset of the analysis taught by Lee who analyzes the products of large molecules which are then reacted to form small molecules which are analyzed. Schneider teaches mass spec can be used to determine both large and small molecules. No novelty is seen in the selection of a known surfactant employed for its known function with the expected result in the method of Lee applied to any analyte such as those shown by Schneider who also employs the same analytical methodology of Lee but employs more common surfactants.

One would have a high expectation of success in employing a method known to analyze small peptides and then analyze "small molecules" by the same method for the same purpose. The point of novelty appears to be the substitution of SDS with the presently elected acid degradable surfactant and this substitution is clearly taught by Lee for the same function as claimed.

Applicant's arguments filed 5/12/08 have been fully considered but they are not persuasive.

Applicants argue that Lee does not teach the analysis of digests of large molecules. Two references are presented to show analysis of large and small molecules are different.

It is the examiner's position that Lee states on page 1 lines 1-2, methods for analysis of large molecules such as proteins or peptides are described. On page 5 last paragraph, sample refers to proteins or peptides. On page 6 line 32 MALDI is an example of mass spec described where MALDI digests the sample whereby large molecules are reacted to produce small molecules and the small molecules are determined. The surfactant employed by Lee is the same surfactant as presently claimed and would have the same function.

Regarding the references presented, it is understood that different classes of compounds lend themselves to different types of analysis. To then consider all compounds as either small or large and generalize analytical methods from there would not apply in many instances. The present invention lies in the selection of a surfactant with a known function and a feature of being functionally inactivated by acid. Many analytical methods employ surfactants for both large and small molecules and selecting any known surfactant in a method which is known to employ surfactants with the expected result would have been obvious. No novelty is seen in function the elected surfactant or in the claimed analytical method.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/
Primary Examiner, Art Unit 1657

Ralph Gitomer
Primary Examiner
Art Unit 1657